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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,030	07/21/1998	BETH P GOLDSTEIN	7732-022-27	1743

7590 12/01/2003

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EXAMINER	
BORIN, MICHAEL L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/120,030	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: _____.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Michael Borin, Ph.D.
Primary Examiner
Art Unit: 1631

Continuation of 2. NOTE: Claims 61-64, drawn to complete clearance of the infection at dosages as claimed in base claims raise issues of enablement and new matter .

Continuation of 5. does NOT place the application in condition for allowance because:

In regard to rejection of claims 4,5,32,41-51,56-60 under 35 U.S.C. 103(a), the rejection is maintained for the following reasons:

In regard to Zygmunt reference, in the absence of an unexpected effect, selection of a particular dosage for a particular way of administration of a pharmaceutical is an art recognized variable which is well within the perview of one of ordinary skill in the art.

In regard to Goldberg reference, Examiner acknowledges applicant's explanation of recalculation of dosages obtained from the reference. However, discussion of effects of lysostaphin on single dogs is not convincing because Table 1 of the reference clearly demonstrates that due to variability of individual response same treatment resulted in different effects - e.g., compare dogs #3,9,11 which received the same dosage but fell into different categories of "well", "relapsed", and "improved". Further, more importantly, the reference teaches (see abstract) that administration of lysostaphin at 5-50 mg/kg at intervals 1-24 hours (i.e., including dosages recited in the claims) resulted in all cases in dogs becoming afebrile (reduced fever) and clinically improved. As the instant claims are drawn to treatment, rather than complete healing (i.e. as in newly proposed claims 61-64), the effect reported in the reference reads on the intended results of the claimed method.

In response to applicant's request for clarification of the discussion of "low" dosages on p. 4 of the preceding Office action, it is not a separate rejection and is presented to indicate another potential rejection.

Rejection of claims 4,5,32,44-47,56-59 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record. The rejection will be moot if the claim amendment is entered..

MICHAEL BORIN, PH.D
PRIMARY EXAMINER